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EXAMINER	
KUMAR, VINOD	
ART UNIT	**PAPER NUMBER**
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,584	SHINOZAKI ET AL.	
	Examiner	Art Unit	
	Vinod Kumar	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/22/05*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20061031* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-19 drawn to a rice-derived promoter with stress inducible promoter activity, a recombinant vector, transgenic plant and a method of making said transgenic plant comprising said promoter, or wherein said promoter consists the nucleotide sequence of SEQ ID NO: 1.

Group II, claims 1-19 drawn to a rice-derived promoter with stress-inducible promoter activity, a recombinant vector, transgenic plant and a method of making said transgenic plant comprising said promoter or wherein said promoter consists the nucleotide sequence of SEQ ID NO: 10.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-II appears to be a nucleotide sequence with stress-inducible promoter activity. However, Yang et al. (Plant Molecular Biology, 50:379-391, 2002) teach a nucleotide sequence of a rice-derived stress-inducible OsEBP-89 promoter and its functional activity in transgenic plants. The sequence taught in the reference would hybridize to instant SEQ ID NO: 1 of claim 1, part (b) under the conditions recited in the claim and further described on page 13 of specification.

Therefore, the technical feature linking the inventions of Groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is SEQ ID NO: 1.

The special technical feature of Group II is SEQ ID NO: 10.

Applicants are reminded that different nucleotide sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute different inventive concepts.

Accordingly, Groups I-II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

During a telephone conversation with Morey Wilds on October 23, 2006 a provisional election was made with traverse to prosecute the invention of Group I with SEQ ID NO: 1. Affirmation of this election must be made by applicant in replying to this Office action. SEQ ID NO : 10 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449 filed on September 22, 2005 is attached to the instant Office action.

Priority

3. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of Application No. Japan 2003-080847, filed 03/24/2003 has been received.

Drawings

4. Applicant's petition to accept color drawings of Figures 2-7 under 37 C.F.R. § 1.84(a)(2) filed in the paper of 9/22/2005 is granted.

ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER

Claim Objections

5. Claims 5, 8, 15, 17 and 19 are objected to because of the following informalities:

In claim 5, it is suggested that abbreviations "P5CS", "AtGolS3" and "NCED" may be designated in full form within parentheses.

Claims 8, 15, 17 and 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, claims 7, 14, 16 and18 are drawn to a transgenic plant, and the host must be plant. Thus claims 8, 15, 17 and19 do not further limit the scope of the claims 7, 14, 16 and 18, respectively.

Appropriate action/corrections are required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-2, 10 and 13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-2 read on a rice derived promoter per se, claims 10 and 13 read on a naturally occurring method for enhancing stress tolerance of a plant by naturally introducing the promoter into a plant which is found in nature and thus, are unpatentable to Applicants. A method for enhancing stress tolerance of a plant can be naturally practiced through naturally occurring hybridization between a plant lacking the promoter and the plant having said promoter. The promoter, as claimed has the same characteristics as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brodgex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested that claim 1 be amended by replacing "A" before "rice-derived" with --An isolated--, to identify a product that is not found in nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "stringent conditions", which is confusing since it unclear what is intended. It is unclear what level of stringency is encompassed by "stringency conditions". Page 13, lines 19-20 of specification gave examples but did not define "stringent conditions".

Claims 4-6 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "genes" which is confusing since the limitation "genes" implies that the structure comprises the coding sequence and the associated promoter, terminator and enhancer encoding regions are also a part of the structure (see The Federal Register, Vol. 66, No. 4, Friday, January 5, 2001 at page 1108, left column, Endnote 13). In the instant case, Applicants do not appear to describe such gene(s) associated nucleic acid sequences. It is suggested that "genes" be amended to "coding sequences".

Claims 7, 14, 16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because claims are incomplete since introducing the vector into any host does not result into a transgenic plant. It is unclear what is intended?

Claims 10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because these claims are incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claims 10 and 13 are missing the essential steps of operably linking a coding sequence encoding a

stress tolerant protein to the claimed promoter and subsequently, expressing said coding sequence under the control of said promoter. The last step only results in a plant comprising the promoter. It is also unclear how a plant transformed with the promoter alone would result in enhanced stress tolerance in the transgenic plant.

Claims 10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "enhancing" which is confusing, since the recitation "enhancing" is a relative term and has no definite meaning. The recitation lacks a comparative basis.

Dependent claims 2-3, 8-9, 11, 14-15 and 17 are also rejected because they fail to overcome deficiencies as discussed above.

Appropriate corrections/clarifications are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a rice-derived promoter as defined in SEQ ID NO: 1, transgenic plant and a method of making said transgenic plant comprising SEQ ID NO: 1 which has dehydration, low temperature or salt-stress induced promoter activity, does not reasonably provide enablement for a) a DNA comprising a nucleotide sequence that hybridizes to SEQ ID NO: 1 under stringent conditions or a transgenic

plant or a method of producing said transgenic plant comprising said DNA sequence b) *any* stress-inducible promoter activity of SEQ ID NO: 1 other than dehydration, low temperature or salt stress inducible activity. The claims contain subject matter which was not described in the specification in such a way as to enable any person skilled in the art to which it pertains, with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to a rice-derived promoter, a recombinant vector, transgenic plant and a method of making said transgenic plant with enhanced stress tolerance comprising SEQ ID NO: 1 or a DNA that hybridizes to SEQ ID NO: 1 under stringent conditions.

The specification teaches isolation of a rice promoter sequence as defined in SEQ ID NO: 1, and preparation of transgenic rice plants comprising SEQ ID NO: 1. The specification further teaches dehydration, salt and cold responsive activity of the promoter in the transgenic plants. See pages 20-29, examples 1-5, Figures 1-9.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

Claim 1 and claims dependent therefrom are directed to any nucleotide sequence that can hybridize to SEQ ID NO: 1 because the stringency conditions recited in claim 1 and further described on page 13, lines 19-20 of specification would encompass hybridization of a DNA comprising a nucleotide sequence that is unrelated to SEQ ID NO: 1. Applicant's attention is also drawn to Maniatis et al. (Molecular Cloning: A Laboratory Manual, Cold Spring Harbor Laboratory (1982), see in particular, pages 387-389) who teach that in order to prevent hybridization of unrelated nucleic acid sequence(s) to a target sequence, hybridization and subsequent washing conditions must be highly stringent. A DNA hybridization to a target sequence under the hybridization conditions of 0.1-1.0x SSC, 50% formamide and 50 °C for 24 hours, followed by 2 washes in 0.1% SDS, 0.1x SSC at 65 °C for 25-30 minutes each is considered highly stringent that would not allow hybridization of an unrelated nucleic acid sequences to the target sequence. In the absence of highly stringent hybridization and washing conditions, an unrelated nucleotide sequence either lacking the promoter activity or exhibiting a non-stress responsive promoter activity would also hybridize to instant SEQ ID NO: 1 under such conditions. This also implies that said unrelated sequences would not be 100% identical in sequence to instant SEQ ID NO: 1 as the hybridizing sequences would encompass deletion, additions or substitutions of one or more nucleotides in the functionally critical part of SEQ ID NO: 1. The specification provides guidance on using SEQ ID NO: 1 in a method of inducing expression of a coding sequence operably linked to SEQ ID NO: 1 in a stress-responsive manner. However, specification does not provide guidance on using a DNA comprising a

nucleotide sequence which is not 100% identical in sequence to SEQ ID NO: 1, in a method of inducing stress-responsive expression of a coding sequence operably linked to said DNA. Neither the state of art at the time the invention was made nor Applicant provide guidance as to which region(s) of SEQ ID NO: 1 should be conserved and which region(s) would tolerate change(s) in one or more nucleotides without abrogating stress-responsive promoter activity. Neither the state of art nor Applicant provide guidance as to how inoperable embodiments can be readily eliminated other than random trial and error. It is well established in the art that changing a single base randomly would abrogate promoter activity. For example, see Kim et al. (Plant Molecular Biology, 24:105-117, 1994) who teach that small alterations in a nos (nopaline synthase) promoter strongly influenced promoter strength. In the absence of adequate guidance, it is highly unpredictable to determine whether all such nucleotide sequences that hybridize to SEQ ID NO: 1 under the conditions encompassed by the claims would exhibit stress-responsive promoter activity. Undue experimentation would have been required by a skilled artisan at the time the claimed invention was made to determine how to use unrelated nucleotide sequences that hybridize to SEQ ID NO: 1, in a method of enhancing stress tolerance in a plant comprising expression of structural and/or regulatory genes under the transcriptional control of said unrelated sequences. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claims 1, 4-6 and 10 and 12-13 are directed to *any* stress-inducible promoter activity of SEQ ID NO: 1. Specification provides guidance on salt, low temperature and dehydration stress responsive activity of SEQ ID NO: 1. Specification does not provide guidance on *any* type of stress-responsive promoter activity of SEQ ID NO: 1 other than those related with salt, low temperature or dehydration stress. It may be emphasized that instant claims encompass abiotic and/or biotic stress response promoter activity of SEQ ID NO: 1. Yamaguchi-Shinozaki et al. (Trends in Plant Science, 10:88-94, 2005) teach existence of different stress-responsive transcriptional regulatory elements within plant genome, and the stress-responsive transcriptional regulatory elements are stress-specific. Furthermore, Logemann et al. (PNAS, 99:2428-2432, 2002) teach that pathogen (biotic stress) overrides UV protection (abiotic stress) by selective transcriptional down-regulation of one or a few metabolic pathways. The reference further teaches that heat shock as well as possibly nutrient depletion overrides both pathogen and UV protection stresses. These teachings of the related art also suggest existence of a complex cross-talk between different stress-responsive promoters during stress conditions. The specification does not provide guidance on *cis*- regulatory elements of SEQ ID NO: 1 that may respond to *any* type of stress condition. In the absence of adequate guidance, undue experimentation would have been required by a skilled artisan at the time claimed invention was made to determine how to use SEQ ID NO: 1 in a method of enhancing stress tolerance in a plant under *any* type of stress condition.

Claims 7-10 and 13-19 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Product that is critical or essential to the practice of the invention, but not included in the claim is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Claims 7-10 and 13-19 do not mention expressing any nucleotide sequence encoding a product under the control of SEQ ID NO: 1 that confers improved characteristics to the plant. See MPEP 2164.089(c).

Claims 10 and 13 and claims dependent thereon are directed to introducing the promoter of SEQ ID NO: 1 into a plant. The specification provides guidance on introducing and expressing stress-inducible coding sequences using the stress-responsive promoter of SEQ ID NO: 1. But specification does not provide guidance on a method of enhancing stress tolerance in a plant in any manner other than transforming a plant with SEQ ID NO: 1 operably linked with a coding sequence encoding a stress-responsive protein. In the absence of guidance, undue experimentation would have been required at the time claimed invention was made to determine how to enhance stress-tolerance in a plant without transforming the plant with a SEQ ID NO: 1 operably linked to a coding sequence encoding a stress-responsive protein.

Claims 4-6 and 12 are directed to structural genes and/or regulatory genes for enhancing stress tolerance and are operably linked to SEQ ID NO: 1 promoter. The specification clearly provides guidance on a method of making and a method of using a vector comprising an abiotic stress-related coding sequence under the operable control

of SEQ ID NO: 1 promoter to produce an abiotic stress tolerant plant. However, the specification does not provide guidance on a method of making, and a method of using a vector comprising multiple structural genes and/or regulatory genes operably linked with SEQ ID NO: 1 promoter. In the absence of guidance, undue experimentation would have been required at the time the claimed invention was made to determine how to make and use a vector comprising multiple structural and/or regulatory genes under the operable control of SEQ ID NO: 1 promoter.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention. Therefore, it is maintained that the claims are not commensurate in scope with the teachings of the specification.

9. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a rice-derived promoter, a recombinant vector, transgenic plant and a method of making said transgenic plant with enhanced stress tolerance comprising SEQ ID NO: 1 or a DNA that hybridizes to SEQ ID NO: 1 under stringent conditions.

The specification describes isolation of a rice promoter sequence as defined in SEQ ID NO: 1, and preparation of transgenic rice plants comprising SEQ ID NO: 1. The

specification further describes dehydration, salt and cold responsive activity of the promoter in the transgenic plants. See pages 20-29, examples 1-5, Figures 1-9.

Claim 1 and claims dependent therefrom are directed to any nucleotide sequence that would hybridize to SEQ ID NO: 1 because the stringency conditions recited in claim 1 and further described on page 13, lines 19-20 of specification would encompass hybridization of a DNA comprising a nucleotide sequence that is unrelated to SEQ ID NO: 1. This implies that an unrelated nucleotide sequence either lacking the promoter activity or exhibiting a non-stress responsive promoter activity would also hybridize to SEQ ID NO: 1 under such conditions. This also implies that said unrelated sequence(s) would not be 100% identical in sequence to instant SEQ ID NO: 1 as the hybridizing sequences would encompass deletion, additions or substitutions of one or more nucleotides in the functionally critical part of SEQ ID NO: 1. Claims 1, 4-6 and 10 and 12-13 are directed to any stress-inducible promoter activity of SEQ ID NO: 1.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and

that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

The specification does not have adequate written description for the genus of sequences that would hybridize to SEQ ID NO: 1 under the conditions recited in the claim and genus of stress-inducible promoter activity of SEQ ID NO: 1 under current written description guidelines, and one skilled in the art cannot reliably predict these structures based on the disclosure of SEQ ID NO: 1. The claims encompass a large number of undisclosed structures of Applicant's broadly claimed genus that have not been described in the specification. Furthermore, Applicants have failed to correlate said undisclosed structures of their broadly claimed genus to the function of stress-inducible promoter activity under any stress condition. Furthermore, Applicants have failed to describe conserved functional domains that are shared by the undisclosed structures of their broadly claimed genus. Applicants have failed to reduce their broadly

claimed genus to practice. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3, and 7-11, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. (Plant Molecular Biology, 50:379-391, 2002).

Claims are broadly drawn to a rice-derived promoter DNA consisting of the nucleotide sequence as shown in SEQ ID NO: 1 or a DNA which hybridizes under stringent conditions to SEQ ID NO: 1, a recombinant vector, transgenic plant and a method for enhancing stress tolerance in said plant comprising said promoter DNA.

Yang et al. disclose a stress-inducible OsEBP-89 promoter derived from rice. The reference further discloses stress (NaCl, salt) inducible promoter activity of said promoter comprising transformation of a rice plant (monocotyledon) with said promoter. The reference further discloses a plant transformation vector, plant cell comprising an expression cassette which comprises a coding sequence (GUS) under the transcriptional control of said stress-inducible promoter. The reference also discloses a method of making transgenic plant comprising said promoter.

The property of hybridization to a DNA under the stringent conditions is inherent to the stress-responsive promoter disclosed the reference.

This rejection is made because DNA hybridization conditions recited in claim 1, part (b) reads on any rice-derived stress-inducible promoter DNA that would hybridize to SEQ ID NO: 1 under such conditions.

Accordingly, Yang et al. anticipated the claimed invention.

11. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Sasaki et al. (NCBI, GenBank, Sequence Accession Number AP005055, Published March 2002) taken with the evidence of Sasaki et al. (NCBI, GenBank, Sequence Accession Number AP005055, Published November 2004).

Claims are broadly drawn to a promoter DNA consisting of SEQ ID NO: 1 which hybridizes under stringent conditions to a DNA comprising a nucleotide sequence, a recombinant vector, or wherein structural and/or regulatory genes function under the control of said promoter.

Sasaki et al. disclose a BAC vector (same as recombinant vector) comprising a rice nucleotide sequence which has 99.7% sequence identity to instant SEQ ID NO: 1. See in particular, nucleotide positions 85270-86335 disclosed in the reference. See in particular, pages 8 and 25-26. This is also evidenced by Sasaki et al. (2004).

The property of stress (dehydration, low temperature or salt) inducible promoter activity is inherent to the sequence disclosed in the reference.

The property of hybridization to a DNA under the stringent conditions is inherent to the promoter sequence disclosed the reference.

This rejection is also made because DNA hybridization conditions recited in claim 1, part (b) reads on any nucleotide sequence that would hybridize to SEQ ID NO: 1 under such conditions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 4-6, and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (Plant Molecular Biology, 50:379-391, 2002) in view of Dubouzet et al. (The Plant Journal, 33:751-763, 2003).

Claims are broadly drawn to a rice-derived promoter DNA consisting of the nucleotide sequence as shown in SEQ ID NO: 1 or a DNA which hybridizes under stringent conditions to SEQ ID NO: 1, a recombinant vector, transgenic plant and a method for enhancing stress tolerance in said plant comprising said promoter DNA, or wherein structural and/or regulatory genes function under the control of said promoter, or wherein said structural and/or regulatory gene is P5CS, AtGolS3, NCED gene, *Arabidopsis thaliana* derived DREB transcription factor or OsDREB derived from rice.

Yang et al. teach a stress-inducible OsEBP-89 promoter derived from rice. The reference further teaches stress (NaCl, salt) inducible promoter activity of said promoter comprising transformation of a rice plant (monocotyledon) with said promoter. The reference further teaches a plant transformation vector, plant cell comprising an expression cassette which comprises a coding sequence under the transcriptional control of said stress-inducible promoter. The reference also teaches a method of making transgenic plant comprising said promoter. See in particular, page 379, abstract; page 380; page 381, figure 1, page 382; page 385, figure 4; page 386, figure 5; page 387, table 1.

Yang et al. do not teach expressing rice OsDREB gene under the control of rice stress-inducible promoter in a transgenic plant.

Dubouzet et al. teach expression of rice OsDREB gene encoding an OsDREB protein in a transgenic plant. The reference further teaches that rice is an important monocot crop and it is important to analyze the DRE/DREB regulon in rice. The reference further teaches the need for generating rice transgenic plants over-expressing

various OsDREB proteins under stress-inducible promoters to obtain transgenic rice plants with increased tolerance to abiotic stresses, such as, high salt, low temperature or dehydration. See in particular, page 751, abstract; page 753, figure 1; page 754; page 755, figures 2 and 3; page 756, figures 4 and 5

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to transform any economically important crop plant including a monocot rice plant with a plant recombinant vector comprising Yang et al. promoter operably linked to Dubouzet et al. OsDREB cDNA using any method of transformation including the one taught by Yang et al. or Dubouzet et al. to obtain a transgenic plant expressing Dubouzet et al. OsDREB protein under the stress-inducible promoter of Yang et al. Given that Dubouzet et al. teach the usefulness of expressing OsDREB genes in transgenic plants including rice, one of ordinary skill in the art would have been motivated to do so for the purpose of obtaining transgenic plants (including monocots) which survive and produce higher yield under abiotic stress conditions of cold, salt or drought with reasonable expectation of success.

Thus, the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

Conclusions

13. Claims 1-19 are rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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